

LWQIC Meeting Minutes
Monday, February 27, 2006

10 am

Room 123

Attendees: Dr. George, Sandy Smole, Bob Goldbaum, John Fontana, Alan Borne, Joe Peppe, Dina Caloggero, Peter Belanger, Kathy Nawn, Peggy DiNatale

Minutes prepared by: Peggy DiNatale, 4/11/06

1. Corrective action review

Bob Goldbaum: FD-05-001

The laboratory had an accident handling a proficiency sample. The laboratory attempted to recover some of the sample and to analyze the remainder of the sample. The laboratory processed the remainder of the PT sample and submitted a result for Total Coliform as "Absent/Negative". Since this initial test analysis was treated as a negative, the next step or confirmatory test was not performed.

The lab's result for this sample was graded as not acceptable. A second PT survey was ordered and analyzed. The result of the second PT survey was acceptable. In the future if the laboratory encounters a problem handling a PT sample, the Lab Supervisor will be notified and the PT provider will be contacted to see if a replacement sample can be obtained.

2. Personnel Qualifications and how HR and QA can assist prior to selection of a candidate

Copies of the CLIA requirements and responsibilities for a Technical Supervisor and a General Supervisor were distributed. Postings for open positions must include the CLIA title and the specific responsibilities for the CLIA title.

Before a position is posted, HR and the Supervisor should give a copy of the posting to QA for review. QA will review it to ensure that the job posting includes the appropriate job responsibilities and appropriate CLIA title. After the Supervisor has identified the preferred candidate, please review with QA again. Also at this point in the process, the applicant should be requested to submit a copy of his/her transcript. The transcript can be reviewed to ensure that the preferred candidate meets the educational requirements for the position. For candidates who have degrees from Universities outside of the US, an outside company must evaluate the transcript to determine the American equivalent of the course work. QA can assist you in identifying companies that are qualified to complete this evaluation.

For CLIA purposes, Dr. George is the Director. Internal Directors will be listed on the CLIA paperwork, which Charlie reviews, as Technical Supervisors. All employees will have three titles: a civil service title, a functional (internal) title and a CLIA title.

QA will place QA documents on the F drive under the "common" folder and a "Quality Assurance" folder. The QA folder will contain two folders: Personnel and SOPs. The Personnel folder will contain the CLIA title descriptions and the CLIA Personnel Appraisal form. The SOP folder will contain the QA SOPs and an electronic version of any attachments for the QA SOPs. The attachments will be available on the F drive, in an electronic version within 2 -3 months.

Lab Certification and CLIA license:

The CLIA license lists which Specialties and Subspecialties in which the laboratory is certified to perform testing of human samples. Our laboratory is certified in the Specialties of Microbiology, Immunology and for the Blood Lead Lab, Clinical Chemistry. The chart below describes the relationship between the Specialty sections and the Sub specialty sections.

Specialty >>>>>>>	Microbiology	Immunology	Clinical Chemistry
Subspecialties >>>>>>>>>>	Bacteriology	Syphilis Serology	Routine Chemistry
	Parasitology	Viral Serology	Toxicology
	Virology	Diagnostic Immunology	Other chemistry
	Mycobacteriology		

CLIA requires that we have one Technical Supervisor for each subspecialty section. The requirements and responsibilities for the Technical Supervisor are different from those of a General Supervisor. During the coming months QA will work with the Directors to review the personnel lists to ensure that we have identified Technical Supervisors and General Supervisors in accordance with CLIA regulations.

3. QA Studies: purpose and scope

QA studies are intended to benefit the laboratory operations. They can be based on a current problem identified by the laboratory staff. The problem log can provide a means to identify recurring problems or a problem that took a significant amount of time to resolve. QA distributed a list of QA Study Projects from all of the labs from 2004 and 2005. Labs can use this list as a reference for a project that may be applicable to their lab.